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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,562	10/09/2001	Joseph P. Desmond III	BSC-186	6009
21323	7590	10/03/2003	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			MATTHEWS, WILLIAM H	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/973,562	Applicant(s) DESMOND ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 38-51 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 17, 18, 38-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7-25-03 have been fully considered but they are not persuasive.

a. With regard to Voss and rejections under 102(b) as well as the primary reference for rejections under 103(a), Applicant contends Voss lacks a wall having three diameters wherein the outer diameters are larger than the intermediate diameter. Furthermore, Applicant attempts to characterize the wall as the intermediate portion and the flanged ends are separate components. Examiner disagrees because figure 5 shows the intermediate wall (length l) and flanged ends (h and t) as a continuous, integral structure. Furthermore Voss lacks a description of separate "flange components" attached to a central conduit. Therefore the "wall" of Voss constitutes all portions from the upper flange to lower flange.

b. With regard to Zilber as a teaching reference in the 103(a) rejections, Applicant contends Zilber does not teach retention rings, instead a helical spring, and that the spring is not at the terminal ends. However, Applicant does point to lines 19-23 of col. 4 wherein Zilber teaches the retention ring extending from the **upper end 16** to approximately 1 cm above the lower end. Although the figure does not show this feature, Zilber teaches placement at the end. Furthermore, Examiner refers to lines 31-35 of col. 9 wherein Zilber teaches annular reinforcement elements in parallel to provide the necessary support as an

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alternative to the spring. In addition, lines 22-28 of col. 4 teach the rings serve to show the position of the device after implantation to ensure proper placement and function.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3,11-12,17,18 are rejected under 35 U.S.C. 102(b) as being anticipated by Voss US PN 4,994,066.

Voss discloses in figures 1-2 and 6-7 a compressible stent having collapsed and expanded states for placement in the prostatic urethra having two terminal ends having larger diameters than an intermediate portion.

Regarding claims 11-12, either end of stent (10) may be considered the first end.

Regarding claims 17-18, radiopaque materials and coatings are described in lines 18-24 of col. 5 and lines 9-20 of col. 6.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4-5,7-9,38-42,44,45,47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss US PN 4,994,066 as applied to claim 1 above, and in further view of Zilber US PN 4,955,859.

Voss discloses a prostatic stent as described above meeting the structural limitations of claims 4-5,7-9, 38-42,44,45, and 47-51, but lacks the express disclosure of retention rings having annular elastic cores and expanded and collapsed states. Zilber teaches in lines 22-28 of col. 4, lines 16-42 of col. 6, lines 47-66 of col. 7, and lines 5-35 of col. 9 a prostatic stent having sidewalls of rubber elastomers, as does Voss, and adds retention rings with annular elastic cores along the length of the stent to provide reinforcement of the stent once implanted to show the position of the device after implantation to ensure proper placement and function.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the elastomer stent disclosed by Voss to include the retention rings taught by Zilber in order to provide sufficient reinforcement once the stent is implanted and to show the position of the device after implantation to ensure proper placement and function.

5. Claims 6 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss US PN 4,994,066 as applied to claim 1 above, and in view of Zilber US PN 4,955,859 as applied to claims 4-5,38,41,42 and in further view of Yachia et al. US PN 5,246,445.

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Voss as modified by Zilber teaches a prostatic stent as described above meeting the structural limitations of claims 6 and 43, but lacks the express disclosure of the retention rings having annular elastic cores made of a nickel titanium alloy. Yachia teaches in lines 29-52 of col. 4 that prostatic stents are well known to use construction materials such as nickel titanium because of its biocompatibility and flexibility.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent disclosed by Voss, as modified by Zilber, to select nickel titanium as the spring material, as taught by Yachia et al. to provide good biocompatibility and flexibility once the stent is implanted.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voss US PN 4,994,066 as applied to claim 1 above, and in further view of Garber US PN 5,269,802.

Voss discloses a prostatic stent, as described above, meeting the structural limitations of claim 10, but lacks the express disclosure of apertures located in the sidewalls. Garber teaches in figure 2 and lines 67 of col. 4 through line 8 of col. 5 a prostatic stent having sidewalls with apertures to provide fluid communication and facilitate urinary incontinence.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent disclosed by Voss by incorporating apertures in the sidewalls as taught by Garber to provide fluid communication and facilitate urinary incontinence.

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7. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voss US PN 4,994,066 as modified by Zilber US PN 4,955,859 as applied to claim 38 above, and in further view of Garber US PN 5,269,802.

Voss as modified by Zilber above discloses a prostatic stent, as described above, meeting the structural limitations of claim 46, but lacks the express disclosure of apertures located in the sidewalls. Garber teaches in figure 2 and lines 67 of col. 4 through line 8 of col. 5 a prostatic stent having sidewalls with apertures to provide fluid communication and facilitate urinary incontinence.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent disclosed by Voss and modified by Zilber, by incorporating apertures in the sidewalls as taught by Garber to provide fluid communication and facilitate urinary incontinence.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

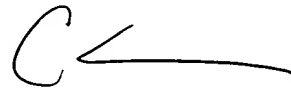
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM

September 30, 2003



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700